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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,261	11/17/2005	Uwe Lehmann	P.P.100	9287

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EXAMINER	
SASAKI, SHOGO	
ART UNIT	PAPER NUMBER
1773	

NOTIFICATION DATE	DELIVERY MODE
11/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

Office Action Summary	Application No.	Applicant(s)	
	10/539,261	LEHMANN ET AL.	
	Examiner	Art Unit	
	Shogo Sasaki	1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/21/2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/16/2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendments to the specification and the claims are acknowledged. Cancellation of claim 6 is also acknowledged. The declarations are also acknowledged.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/21/2010 has been entered.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, "the channel having a diameter (cross sectional diameter as stated by applicant in the reply filed 9/9/09: page 10, paragraph 4) greater than the path which an analyte molecule covers via diffusion on its way between 2 sequential turning points" in claims 1, 11 and 19 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Also see 112 rejections.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Information Disclosure Statement

4. The information disclosure statement (IDS) filed on 12/21/2007 fails to comply with 37 CFR 1.98(a)(3) because it does not include concise explanations of the relevance for some of the non-patent literature cited therein, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information. The reference numbers R3, R6 and R10 included in the IDS filed on 12/21/2007 are not in the English language, however they do not include

concise explanations of the relevance. The IDS have been placed in the application file, but the abovementioned information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-5 and 7-20 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling.

Claims 1, 11 and 19 are directed towards methods of directing molecules to separation columns. However said claims do not claim steps of providing structural elements that define a column having a channel to be considered a column capable of separating analytes. Such structural element(s) is/are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. It is unclear how a channel including curves with unspecified dimension or material can separate molecules.

Furthermore, it is unclear how molecules are "directed" to separation columns recited in claims 1, 11 and 19. Is the molecule pumped into the separation columns by other structure with force, or by mere diffusion of the molecules in/from space? It is also unclear if the molecules recited in the preamble and the step of directing are the same molecules of the fluid stream recited in line 3.

7. Claims 1-5 and 7-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1, 7, 8, 16, 17 and 19 recites "diameter." It is not clear if the diameter in said claims, for e.g., recited by "diameter of the channel" or "diametrically opposite the curves," refers to the diameter defined by a cross-sectional area of a channel/conduit having a circular conduit cross-section; or it is the diameter defined by a channel/conduit formed into a shape having turning points (See Figures 2-4 of instant invention.). It is also not clear what structure or what part of what structure is greater than the "path." The examiner respectfully asserts that it is physically impossible to have a channel having a diameter (in either interpretation of the diameter stated above) greater than the path which an analyte molecule covers via diffusion on its way between 2 sequential turning points, as claimed in claims 1, 11 and 19.

Applicant stated that the claimed diameter is the cross sectional diameter in the reply filed 9/9/09: page 10, paragraph 4. The examiner fails to see why applicant is not amending the claims to clarifying the issue.

Applicant originally defines the turning point as "a point at which the curved direction of the channel and therefore also the flow direction of the fluid stream flowing through the channel changes to the particular other direction" (page 4, lines 8-12). The

curved path will inherently have infinite numbers of turning points at corresponding numbers infinitesimal curvatures. The direction of the path on a tuning point changes at all times. Applicant defines the curve as "**any** curved region of the channel having the same curve direction, and such a curve lies between two directly sequential turning points, which mark a change to the particular other direction." (page 4, lines 14-18). The direction of the path along the curve changes at all times.

The turning points; the curve; and the relationships between the two depicted in the figures appears to be different from how they are defined in the specification. The reference characters 7a, 8 and 8a in Fig. 2-4 appear to be at the linear path defined by two joined round paths. It is unclear what path between which tuning points is considered a curve. In light of above assumed definitions of the diameter:

(1) It is unclear how a diameter of a conduit could be greater the length defined by the path between two turning points (i.e., the section of the column where molecules travel/diffuse along said path); and

(2) It is unclear how a diameter defined by a channel/conduit formed into a round shape could be greater than the length defined by the path between two turning points (i.e., the section of the column where molecules travel/diffuse along said path). The diameter of a material formed into a round shape is defined by circumferential structure of said material formed into a round shape. The examiner fails to see how this diameter could be greater than the path, which corresponds to the circumference correlated to said diameter.

In response to page 9, paragraph 4 and page 11, paragraph 2, the claim limitation essentially says/reads in the same way the examiner is asserting above. The claims recites that "the diameter of the channel is greater than the path which an analyte molecule covers via diffusion on its way between 2 sequential turning points." (It is noted that said limitation is also not the same thing disclosed in [0011-0012] of the specification.) The limitation is interpreted to mean that the diameter of the channel is greater than the path of the molecule along the channel.

In response to page 10 and 11, the examiner fails to see how a molecule(s) (merely by directing them to the channel or in any other situation) diffusing through the path of the channel moves in the exemplified dotted path illustrated in figure sheets filed 5/21/2010. The molecules diffusing, in reality, are in Brownian motion (Also see Einstein formula in [0011] of the instant application.). The diffusion, thus the direction of molecules having kinetic energies depends on variety of factors, such as temperature; pressure; types of fluid/analyte and carrier gases; packing materials in the column; and etc. The examiner fails to see how a structure of a channel can be defined by the theoretical (perhaps hypothetical) diffusion scenarios exemplified by the figures. In addition, merely "directed" (without any motive force) molecules would diffuse in all directions, not in the direction indicated by the dotted lines. Let alone, a volume of gas directed to even a micro-sized channel would contain molecules in the number of 10^{20-21}. The collisions among molecules alone appear to invalidate the scenarios.

8. Claims 1-5 and 7-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation "channel comprising opposing curves comprising turning points where the flow direction of the fluid stream flowing through the channel changes to the particular other direction, ***wherein*** the diameter of the channel is greater than the path which an analyte molecule covers through diffusion on its way between two sequential turning points located at the beginning of sequential curves that each have the same curvature" in claims 1, 11 and 19 was not described in the original specification and the claims (See paragraph 7 above.).

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-5 and 7-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 11 and 19, it is unclear how molecules are "directed" to the separation column. Is the molecule pumped into the separation columns by other structure with force, or by mere diffusion of the molecules in/from space?

Furthermore, it is unclear if the molecules recited in the preamble and in the step of directing are the same molecules of the fluid stream recited in line 3.

Much of the structural limitations in the step of directing molecules to the column attempt to define the structure of the channel of the separation column, specifically the curves of the channel having turning points and the diameter of the channel, in terms of how the fluid travels within the channel; and diffusive features of a fluid to be analyzed. It is unclear how the fluid flows through the channel can possible structurally define the channel of the column; and the curvature of the curves of the channel. The diffusion length of a molecule in a separation column is dependent on various factors, such as temperature; pressure; types of fluid/analyte and carrier gases; packing materials in the column; and etc. (See page 5 of instant application). As a result of this large number of unknown factors: the structure of the curves on the channel; the size of the claimed channel diameter; and the structural relationships between curves with turning points and the diameter of the channel are all unclear, thus all leading to indefinite claims.

Regarding claims 11, 12 and 14, it is unclear how a micro-chromatogram defined by a continuous column/channel formed into multiple curves and loops comprises multiple columns. According to the specification, the chromatogram/column shown in figures is defined by a channel formed into loops and curves that are bent and oriented in series and/or parallel configuration.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-5 and 7-20 are rejected under 35 U.S.C. 102 as being unpatentable over by the Applicant's Admission of Prior Art (Fig. 1; and page 10, line 11 - page 11, line 6.).

Regarding claims 1-5 and 7-20, the Applicant's Admission of Prior Art (AAPA) discloses a separating column having a channel with turning points which read on currently presented claims.

A statement by an applicant in the specification or made during prosecution identifying the work of another as "prior art" is an admission which can be relied upon for both anticipation and obviousness determinations, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of 35 U.S.C. 102.

Prior Art Cited

13. It is noted that U.S. 6,153,073 cited in this office action (See Form 892) discloses sinusoidal separation columns very similar to the device disclosed in the figures of the instant application.

Response to Arguments

14. Applicant's arguments filed 5/21/2010 have been fully considered.

15. It is noted that applicant did not respond to paragraph 2 of the last office action regarding IDS filed on 12/21/2007.

16. The objections to the claims and the specification are withdrawn.

17. The content of the declaration by Uwe Lehman filed 5/21/2010 is not for this application. It states that the declaration is for U.S. application number 10-541145. However, in view of paragraphs 7-9, the 102(a) and (b) rejections in view of Lehmann et al. (IDS: Sensor 2003 Proceedings, 157-161) are withdrawn. The examiner requests a new declaration with correction for the application number in paragraph 1.

18. The declaration by Dr. Lars Birken has been considered. It is noted that the language of the translation of DE 10303107.3 is substantially identical to the specification filed on 6/15/2005.

19. Applicant's arguments have been fully considered but they are not persuasive.

The 112 rejections are maintained (It is noted however that 112 (2) rejections of claims 4, 9, 10, 15 and 19 regarding antecedent basis and etc are withdrawn.). However since the claims are now directed to methods of directing molecules to separation columns, the rejections are revised and applicant's argument are addressed in the 112 section of this office action.

Even though applicant amended claims so that said claims are now directed to methods of using the disclosed apparatus, the method claims 1, 11 and 19 are merely

directed towards "using" the apparatus. That is similar to "use" claims (MPEP 2173.059(q)). Said claims only include a step of directing molecules to an apparatus. This appears to only imply that the method only includes a step of providing the apparatus and somehow the molecules are "directed" to the columns. Much of the structures recited in said methods do not overcome previous 112 issues. Said claims do not even include how the analyte are directed towards the column. The dependent claims merely structurally limit the separation columns provided in claims 1, 11 and 19.

Applicants arguments (pages 9-14) are based on the structure (the channel) of invention, which is defined in terms of how the fluid travels within the channel; and diffusive features of a fluid to be analyzed. How the fluid flows through the channel does not structurally define the inflection and the curvature of the curves. In the latter case, the diffusion length of a molecule in a separation column is dependent on various factors, such as temperature; pressure; types of fluid/analyte and carrier gases; packing materials in the column; and etc (Please also see international search report provided by applicant [2nd Paragraph of Box VIII in PCT/IPEA/409].). As a result of this large number of unknown factors: the structure of the curves on the channel; the size of the claimed channel diameter; and the structural relationships between curves with turning points and the diameter of the channel are all unclear, thus all leading to indefinite claims. The claims are unclear that one cannot access the scope of the claims. The claims are interpreted to mean a column/chromatogram comprising a channel having opposing curves. (Please also see entire 112(1) and 112(2) rejections above.)

Furthermore, the examiner respectfully asserts that it is physically impossible to have a channel having a diameter (cross sectional diameter as stated by applicant in the reply filed 9/9/09: page 10, paragraph 4) greater than the path which an analyte molecule covers via diffusion on its way between 2 sequential turning points, as claimed in claims 1, 11 and 19.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shogo Sasaki whose telephone number is (571)270-7071. The examiner can normally be reached on Mon-Thur, 10:00am-6:30pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SS

11/17/2010

/Brian R Gordon/

Primary Examiner, Art Unit 1773